UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO., INC., Plaintiff, v. SANOFI-AVENTIS, SANOFI-AVENTIS U.S., LLC and AVENTIS PHARMACEUTICALS, INC., Defendants.	Civil Action No. 07-cv-7343 (HB)(AJP) Hon. Harold Baer, U.S.D.J. ECF CASE

DEFENDANTS SANOFI-AVENTIS U.S. LLC AND AVENTIS PHARMACEUTICALS INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT

Defendants sanofi-aventis u.s. llc and Aventis Pharmaceuticals Inc. (collectively, "Aventis"), by and through their undersigned attorneys, hereby respond to Louisiana Wholesale Drug Co., Inc's ("Plaintiff") Class Action Complaint (the "Complaint"), as follows:

PRELIMINARY STATEMENT

Aventis submits this Answer in accordance with Magistrate Judge Andrew J. Peck's Order dated December 21, 2007. Aventis notes that sanofi-aventis u.s. llc and Aventis Pharmaceuticals Inc. moved to dismiss the Complaint for failure to state a claim (the "Motion to Dismiss") on October 15, 2007; that the fully briefed Motion to Dismiss was submitted to the Court on November 15, 2007; and that the Motion to Dismiss is set for oral argument before the Court on January 4, 2008. Pursuant to Magistrate Judge Peck's December 21, 2007 Order, this Answer is filed without prejudice to the pending Motion to Dismiss.

Aventis denies each and every allegation of the Complaint not specifically admitted below. Aventis responds to Plaintiff's allegations in like-numbered paragraphs as follows:

CLASS ACTION COMPLAINT

Plaintiff Louisiana Wholesale Drug Co., Inc. ("Plaintiff" or "Louisiana Wholesale"), on behalf of itself and all others similarly situated, for its Class Action Complaint ("Complaint") against defendants Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc. (collectively "Aventis" or "Defendant"), alleges as follows based on: (a) personal knowledge; (b) the investigation of Plaintiff's counsel; and (c) information and belief:

I. *NATURE OF THE ACTION*

1. *This is a civil antitrust action seeking treble damages arising out of Defendant's unlawful exclusion of AB-rated generic competition from the market for leflunomide, a pharmaceutical drug used for treatment of active rheumatoid arthritis (RA) to reduce signs and symptoms, and to retard structural damage as evidenced by X-ray erosions and joint space narrowing. Leflunomide is sold by Aventis under the brand name Arava, and sold by generic manufacturers under the chemical name leflunomide.*

1. Paragraph 1 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 1 of the Complaint. Aventis admits, however, that leflunomide is a pharmaceutical compound used in the treatment of rheumatoid arthritis ("RA") to reduce the signs and symptoms of, and to retard structural damage associated with, the disease; that Aventis sells leflunomide under the brand name Arava; and that generic manufacturers sell the product under the chemical name leflunomide.

2. *Aventis, and its predecessor entities, have been participants in the pharmaceutical industry for many years and have had, at all relevant times, a very sophisticated understanding of the economics and other inter-workings of this industry. For instance, Aventis is, and has been, fully aware of the realities of competition from AB-rated generic versions to branded drugs, and the inevitable significant decline in sales of a brand name drug once AB-rated generic versions of that drug come to market.*

2. Aventis DENIES each and every allegation of Paragraph 2 of the Complaint. Aventis admits, however, that it (and/or certain of its predecessors) have participated in the pharmaceutical industry for many years. Aventis further admits that AB-rated generic drugs compete with branded drugs and may cause a decline in branded drug sales.

3. *More specifically, AB-rated generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective, as their brand name counterparts. This is due to the fact that AB-rated generic drugs are "bioequivalent" to their brand name drug counterparts, meaning they provide the same amount of active ingredient into a patient's bloodstream for the same amount of time as the branded drug.*

3. Aventis DENIES each and every allegation of paragraph 3 of the Complaint. Aventis admits, however, that the Food and Drug Administration ("FDA") requires an AB-rated generic version of a brand name drugs to contain the same active ingredient as the brand name version of the drugs. Aventis further admits that the FDA deems an AB-rated generic version of a brand name drug to be as safe and effective as its brand name counterpart. Aventis also admits that the FDA requires an AB-rated generic drug to be bioequivalent to its brand-name counterpart as that term is defined in 21 C.F.R. § 320.1(e).

4. *The only material difference between generic drugs and their brand name counterparts is price. Generics are typically far less expensive than their brand counterparts, especially when there are multiple generic competitors on the market. As a result, AB-rated generics constitute both, (a) an opportunity for drug purchasers and consumers to obtain enormous cost savings, and (b) a serious threat to the monopoly power and profits of the manufacturer of the brand name drug facing generic competition. Indeed, AB-rated generic versions of brand name drugs typically take 80% or more of the sales of a brand name drug within a year of generic entry.*

4. Paragraph 4 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 4 of the Complaint. Aventis admits, however, that generic drugs tend to be less expensive than the corresponding brand-name drug.

5. *Knowing these realities of the pharmaceutical industry, Aventis was keenly aware that it would lose a substantial amount of its sales of Arava very quickly once AB-rated generics versions came to market. As described in more detail below, in order to delay this inevitable loss of sales revenue, Aventis engineered a scheme whereby it would, inter alia, delay generic competition by filing an objectively baseless (i.e., sham) Citizen Petition for the express purpose, and with the express intent, of delaying the FDA' s final approval of the various leflunomide Abbreviated New Drug Applications ("ANDAs") which sought permission to market and sell AB-rated generic versions of Arava.*

5. Paragraph 5 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 5 of the Complaint.

6. *Aventis knew, based on the FDA's limited resources and practice of carefully considering all Citizen Petitions purporting to indicate threats to the public health before granting final approval to ANDAs – even frivolous ones such as at issue here – that the mere filing of a Citizen Petition would immediately delay FDA final approval of ANDAs seeking approval for AB-rated generic versions of Arava.*

6. Aventis DENIES each and every allegation of Paragraph 6 of the Complaint.

7. *That is precisely what occurred in this case. On the eve of FDA approval of multiple ANDAs for leflunomide in March 2005, Aventis filed an objectively baseless, sham Citizen Petition with FDA regarding these ANDAs. As was, and is, FDA's practice, the FDA considered and ruled on the Citizen Petition prior to granting final approval to the ANDAs at issue. As expected, the FDA found that Aventis' Citizen Petition was completely without merit on September 13, 2005. See Exhibit 1. Immediately upon this ruling by FDA, the AB-rated generic versions of leflunomide were given final approval by FDA and came to market. But, Aventis obtained its desired result: FDA approval of the multiple leflunomide ANDAs, and hence market entry, was delayed by at least five (5) months.*

7. Paragraph 7 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 7 of the Complaint and DENIES that its March 31, 2005 citizen petition was "an

objectively baseless, sham" petition. Aventis admits, however, that its March 31, 2005, citizen petition with the FDA asked the FDA to hold generic manufacturers to the same safety and effectiveness standards to which the FDA held Aventis: namely, to require the generic manufacturers to seek approval of a 100mg loading dose or establish *in vivo* bioequivalence between five 20mg leflunomide tablets and one Arava 100mg tablet. Aventis further admits that two generic manufacturers submitted comments on the petition; one comment observed that the petition was credible on its face, while the other implicitly acknowledged the objective merit to the petition by proposing an alternative remedy in response to it. Aventis further admits that on September 13, 2005, the FDA denied the remedy sought by Aventis' petition and adopted the remedy suggested by one of the generic manufacturers (thereby rendering the petition moot), and subsequently approved the generic manufacturers' ANDAs.

8. *Once AB-rated generic versions of leflunomide came to market, Aventis lost approximately 80% of its $235 million annual sales of Arava in the U.S. to AB-rated generic leflunomide within three months.*

8. Aventis DENIES each and every allegation of Paragraph 8 of the Complaint.

9. *Thus, as a result of its illegal scheme, and in violation of §2 of the Sherman Act, Aventis: (a) illegally maintained monopoly power in the market for leflunomide in the United States for at least five (5) months; (b) fixed, raised, maintained, and/or stabilized the price of leflunomide at supra-competitive levels; and (c) overcharged Plaintiff and members of the Class (i.e., direct purchasers of Arava) by millions of dollars by depriving them of the results of competition from cheaper generic versions of Arava.*

9. Paragraph 9 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 9 of the Complaint.

10. *Aventis' extended period of monopoly power in the leflunomide market was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a legally-obtained market exclusivity, a superior product, business acumen or historic accident.*

10. Paragraph 10 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 10 of the Complaint.

II. *JURISDICTION AND VENUE*

11. *This Complaint is filed, and these proceedings are instituted, under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages in the form of overcharges, and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiff and members of the Class of direct purchasers of Arava resulting from the violation by Aventis, as alleged herein, of Section 2 of the Sherman Act, 15 U.S.C. §2. The jurisdiction of this Court is based upon 28 U.S.C. §~ 1331 and 1337(a), and 15 U.S.C. §15.*

11. Paragraph 11 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 11 of the Complaint. Aventis admits, however, that Plaintiff purports to bring claims against Aventis under Section 4 of the Clayton Act, 15 U.S.C. § 15, and Section 2 of the

Sherman Act, 15 U.S.C. § 2; and that this Court has subject matter jurisdiction over the Complaint pursuant to 15 U.S.C. § 15, and 28 U.S.C. §§ 1331 and 1337(a).

12. *Aventis transacts business around the world, and within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).*

12. Aventis DENIES each and every allegation of Paragraph 12 of the Complaint. Aventis admits, however, that venue is proper in this district.

III. *THE PARTIES*

13. *Plaintiff Louisiana Wholesale Drug Co., Inc. ("Louisiana Wholesale") is a corporation organized under the laws of the State of Louisiana and is located at 20851-49, South Service Road, in Sunset, Louisiana 70584. Louisiana Wholesale purchased Arava directly from Aventis during the Class Period, as defined below, and was injured in the form of overcharges by the illegal conduct described herein.*

13. Paragraph 13 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 13 of the Complaint and therefore DENIES each and every allegation contained therein. Aventis further DENIES that Plaintiff and any putative class members are entitled to the relief sought in the Complaint or to any other relief whatsoever from Aventis. Aventis admits, however, that

Louisiana Wholesale Drug Co., Inc. purchased Arava directly from Aventis at various times during the period alleged in the Complaint.

14. *Defendant, Sanofi-Aventis, located at 174, avenue de France, 75013 Paris, France, is one of the world's largest pharmaceutical companies. Sanofi-Aventis sold, and/or authorized the sale of, Arava in the United States.*

14. Aventis DENIES each and every allegation in Paragraph 14 of the Complaint. Aventis admits, however, that sanofi-aventis is a corporation organized under the laws of and doing business in France, and that it has offices at 174, avenue de France, 75013 Paris, France.

15. *In the United States, Sanofi-Aventis conducts business and markets Arava through its affiliates, Defendant Sanofi-Aventis U.S. LLC, and/or Defendant Aventis Pharmaceuticals, Inc., incorporated under the laws of the State of Delaware, each with their principal place of business in the United States, in Bridgewater, New Jersey.*

15. Aventis DENIES each and every allegation of Paragraph 15 of the Complaint. Aventis admits, however, that sanofi-aventis u.s. llc and Aventis Pharmaceuticals Inc. are Delaware corporations with their principal place of business in Bridgewater, New Jersey, and that sanofi-aventis u.s. llc markets and sells Arava in the United States.

IV. *CLASS ACTION ALLEGATIONS*

16. *Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:*

b. *All persons or entities in the United States who purchased 10 mg or 20 mg Arava tablets directly from Aventis (or any of its predecessors or affiliates) at any time*

from March 2005, until the anticompetitive effects of Defendant's conduct ceased (the "Class").

c. *Excluded from the Class are Defendant, and its predecessors, it officers, directors, management, employees, subsidiaries, parent or affiliates, and all federal governmental entities.*

16. Aventis DENIES each and every allegation of Paragraph 16 of the Complaint. Specifically, Aventis DENIES that this action properly may be maintained as a class action under any subsection of Rule 23 of the Federal Rules of Civil Procedure and that the proposed class definition is proper or legally sufficient. Aventis further DENIES that Plaintiff and any putative class members are entitled to the relief sought in the Complaint or to any other relief whatsoever from Aventis.

17. *Members of the Class are so numerous that joinder is impracticable. Plaintiff believes there are at least dozens of Class members spread across the United States. Moreover, the members of the Class are readily identifiable from information and records in the possession of Defendant.*

17. Paragraph 17 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 17 of the Complaint. Aventis admits, however, that the identity of persons who purchased 10mg and 20mg tablets directly from it during the period alleged in the Complaint may be ascertained from the transactional data Aventis has produced already to Louisiana Wholesale.

18. *Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged in the same way by the same wrongful conduct of*

Aventis, i.e., they paid artificially inflated prices for leflunomide and were deprived of the benefits of competition from cheaper generic versions of Arava as a result of Aventis' wrongful conduct.

18. Paragraph 18 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 18 of the Complaint

19. *Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiffs interests are coincident with, and not antagonistic to, those of the Class.*

19. Paragraph 19 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 19 of the Complaint.

20. *Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.*

20. Paragraph 20 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 20 of the Complaint and therefore DENIES each and every allegation contained therein.

21. *Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Aventis has acted on*

grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendant's wrongful conduct.

21. Paragraph 21 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 21 of the Complaint.

22. *Questions of law and fact common to the Class include:*

a. whether Defendant illegally maintained its monopoly power by improperly delaying generic entry through, inter alia, the filing of a sham Citizen Petition;

b. *whether direct proof of Defendant's monopoly power is available, and if available, whether it is sufficient to prove Defendant's monopoly power without the need to also define a relevant market;*

c. *to the extent a relevant market or markets must be defined, what that definition is or those definitions are;*

d. *whether the activities of Defendant as alleged herein have substantially affected interstate commerce; and*

e. *whether, and to what extent, Defendant's conduct caused antitrust injury, and if so, the appropriate measure of damages.*

22. Paragraph 22 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 22 of the Complaint.

23. *Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class*

mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

23. Paragraph 23 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 23 of the Complaint.

24. *Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.*

24. Paragraph 24 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis is without sufficient information or information to form a belief concerning the basis for Plaintiff's alleged knowledge but DENIES each and every allegation of Paragraph 24 of the Complaint in any event.

V. *FACTUAL ALLEGATIONS*

A. *The Regulatory Structure Pursuant to Which Generic Substitutes for Brand Name Drugs Are Approved*

25. *Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.*

25. Aventis admits that the Food, Drug, and Cosmetic Act ("FDCA"), and specifically 21 U.S.C. §355(a), prohibits the manufacturer of a new drug from introducing (or

delivering for introduction) a new drug into interstate commerce without filing a New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") and securing FDA approval of the application. Aventis further admits that 21 U.S.C. 355(b) requires all NDAs to include (among other things) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use, as well as any applicable patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug..

26. *In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").*

26. Aventis admits that the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act") amended the FDCA.

27. *The purpose of the Hatch-Waxman Act was twofold. First, Congress sought to expedite generic competition, and thereby reduce healthcare expenses nationwide, where a generic product could be developed that did not infringe any existing legitimate patent. Second, Congress wanted to protect the incentive of pharmaceutical companies to create new and innovative products. The Hatch-Waxman Act achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies.*

27. Aventis is without knowledge or information as to the number or scope of purposes for the Hatch-Waxman Act and therefore DENIES the allegations of the first sentence of Paragraph 27 of the Complaint. The second sentence of Paragraph 27 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis admits that the Hatch-Waxman Act amended the FDCA to permit (among other things) generic drug manufacturers to file ANDAs prior to the expiration of certain patent rights belonging to branded drug manufacturers. Aventis further admits that the Hatch-Waxman Act purported to balance the need for innovation against reducing healthcare expenses and that the rate of generic product launches has increased since the enactment of the Hatch-Waxman Act. Aventis DENIES the remainder of the allegations in Paragraph 27 of the Complaint.

28. *Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").*

28. Aventis DENIES each and every one of the allegations in Paragraph 28 of the Complaint. Aventis admits, however, that the Hatch Waxman Act created the ANDA process by which prospective generic drug manufacturers could rely, assuming other conditions were met, on the investigations conducted by the original NDA applicant to show whether or not such drug is safe for use and whether such drug is effective in use.

29. *The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer, however, must*

demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand name drug. Bioequivalency is a demonstration that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the brand drug counterpart.

29. Aventis admits the allegations contained in the first sentence of Paragraph 29 of the Complaint. Aventis DENIES the remainder of the allegations in Paragraph 29, although it admits that the FDA requires a generic drug manufacturer to demonstrate that the drug it proposes to manufacture is bioequivalent to its brand-name counterpart as that term is defined in 21 C.F.R. § 320.1(e).

30. *As a counter-balance to this abbreviated process for bioequivalent generic drugs, Hatch-Waxman streamlined the process for a brand name manufacturer to enforce legitimate patents it may have that cover its brand name drug against infringement by generic manufacturers. Hatch-Waxman also provided that, under certain conditions not present in this case, the FDA would refrain from granting a generic manufacturer final approval to market or sell its generic version of a brand name drug for up to 30 months if patent litigation over those drugs ensues.*

30. The first sentence of Paragraph 30 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis admits that the Hatch-Waxman Act contains provisions (not applicable here) permitting a branded drug manufacturer to sue an ANDA applicant, and prohibiting the FDA from finally approving the ANDA for 30 months following initiation of any such suit.

31. *Hatch-Waxman also provides brand name manufacturers with several means, in addition to traditional patent rights, to obtain legitimate protection from generic competition for set, and specifically limited, periods of time. For example, each approved NDA provides the owner of that drug three (3) years of exclusivity during which time no generic can even file an ANDA. See 21 U.S.C. § 355(j)(5)(F)(iii). For pioneer drugs that are truly new or innovative in that they make use of a never-before-approved chemical entity or moiety – as opposed to an NDA relating to the far more common reformulations or dosage changes for existing drugs – the FDA grants an "New Chemical Entity" ("NCE") exclusivity period of five (5) years. See 21 U.S.C. § 355(j)(5)(F)(ii). The FDA gives six (6) months of additional exclusivity to a branded drug that satisfactorily complies with an FDA request to conduct pediatric studies. See 21 U.S.C. § 355a(c)(2)(A); see also, Barr Laboratories, Inc. v. Thompson, 238 F.Supp.2d 236, 240 - 241 (D.D.C. Dec 18, 2002). In addition, if an NDA drug treats a rare condition, FDA may grant an additional two (2) years of Orphan Drug exclusivity.*

31. Aventis admits that the FDCA provides differing periods of marketing exclusivity for approved NDAs, and restricts the ability of generic manufacturers to file ANDAs during any such periods.

B. *Generic Versions of Brand Name Drugs are Significantly Less Expensive Than, and Take Significant Sales Directly From, the Corresponding Brand Name Versions*

32. *Typically, AB-rated generic versions of brand name drugs are priced significantly below the brand name counterparts. Because of the price differentials, and other institutional features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their brand name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease significantly because of*

competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generics is dramatic.

32. Aventis DENIES each and every allegation of Paragraph 32 of the Complaint. Aventis admits, however, that AB-rated generic drugs compete with branded drugs and may cause a decline in branded drug sales.

33. *An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (i.e., the Hatch-Waxman Act) and most state legislatures (i.e., Drug Product Selection, or "DPS laws"), pharmacists may (and, in most states, must) substitute an AB-rated generic version of a drug for the brand name drug without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated "Dispense as Written," or "DAW"). Indeed, both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously (a) engaging in the type of heavy promotion or "detailing" typically done by brand name manufacturers, and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.*

33. Aventis is without knowledge or information as to the allegations in Paragraph 33 of the Complaint and therefore DENIES each and every one of them.. Aventis admits, however, that Congress and state legislatures encourage the use of generic versions of brand-name drugs.

34. *Generic competition enables direct purchasers to (a) purchase generic versions of brand name drugs at substantially lower prices, and/or (b) purchase the brand name drug at*

reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand name sales. Consequently, brand name drug manufacturers have a strong interest to use various tactics, including the tactics alleged herein, to delay the introduction of AB-rated generic competition into the market.

34. Aventis DENIES each and every allegation of Paragraph 34 of the Complaint. Aventis admits, however, that generic versions of brand-name drugs tend to be priced below the corresponding brand-name drug.

C. *Citizen Petitions to the FDA*

35. *A person or entity, such as a pharmaceutical company, may file a Citizen Petition with the FDA requesting, among other things, that the FDA take, or refrain from taking, administrative action. See 21 CFR 10.30. Citizen Petitions may, for example, request that a pending ANDA not be approved. Citizen Petitions are intended to provide an opportunity for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product anytime before, or after, its market entry.*

35. Aventis DENIES each and every one of the allegations of Paragraph 35 of the Complaint. Aventis admits, however, that pursuant to 21 C.F.R. § 10.30, any person or entity may file a petition requesting that the FDA take (or refrain from taking) a particular action, including action with respect to an ANDA.

36. *Federal regulations provide a 180 day period for the FDA Commissioner to respond to each Citizen Petition. See 21 CFR l0.30(e)(2). The FDA may approve the Citizen*

Petition request, approve it in part, deny the request, or provide a tentative response with an estimate on a time for a full response.

36. Aventis admits that FDA regulations provide that the Commissioner of the FDA shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either: (i) approve the petition; (ii) deny the petition; or (iii) provide a tentative response. The FDA Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. 21 C.F.R. §10.30(e)(2). Aventis further admits that FDA regulations specifically state that the filing of a citizen petition *shall not* "stay or otherwise delay *any* administrative action by the Commissioner" unless the Commissioner determines that a stay is in the public interest and stays the action. 21 C.F.R. § 10.35(d) (emphasis added).

37. *Reviewing and responding to these petitions is often a resource-intensive and time consuming task because the FDA must, in addition to its already-existing workload, (a) research the Citizen Petition's subject matter, (b) examine scientific, medical, legal and sometimes economic issues, (c) consider public responses to the Citizen Petition, and (d) coordinate internal agency review and clearance of the petition response.*

37. Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 37 of the Complaint and therefore DENIES each and every allegation contained therein.

D. *Use of Citizen Petitions by Named Brand Drug Manufacturers As a Mechanism to Forestall Generic Competition*

38. *In recent years, the Citizen Petition process has been subject to misuse by some brand name pharmaceutical manufacturers as a tactic to extend their monopolies on certain brand name brand drugs.*[1] *Often, Citizen Petitions by rival companies do not raise legitimate concerns about the safety or efficacy of generic products, but instead seek to preserve monopolies after the end of statutorily-granted patent or FDA exclusivity period(s). These Citizen Petitions are often filed on the eve of FDA approval of an ANDA for competing AB-rated generic drugs. Final approval of a pending ANDA is typically delayed for several months, but may be delayed for over a year, while the FDA evaluates the Citizen Petition.*

38. Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 38 of the Complaint and therefore DENIES each and every allegation contained therein. Aventis admits, however, that the staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission issued a Comment in the year 2000 on a proposed change to the regulations governing citizen petitions.

39. *Delayed generic competition is a lucrative outcome for an incumbent brand name manufacturer facing impending competition from an AB-rated generic(s). The cost of filing an improper, sham Citizen Petition is trivial compared to the value of securing several additional months of monopoly profits.*

[1] *See Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, at http://www.ftc.gov/be/V000005.Pdf, at p. 1, et seq.*

39. Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 39 of the Complaint and therefore DENIES each and every allegation contained therein.

40. *FDA officials have acknowledged ongoing abuses of the Citizen Petition process. FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency, he had "seen several examples of Citizen Petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."*[2]

40. Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 40 of the Complaint and therefore DENIES each and every allegation contained therein. To the extent that Paragraph 40 relies on statements contained in the public record, those statements speak for themselves.

41. *In July 2006, Gary Buehler, Rhp., Director of the Office of Generic Drugs Center for Drug Evaluation and Research ("CDER") at the FDA, noted that of 42 Citizen Petitions raising issues about the approvability of generic products, "very few ... have presented data or analysis that significantly altered FDA's policies." Of these 42, only three (3) petitions led to a*

[2] *These comments were made by FDA Chief Counsel Sheldon Bradshaw in a speech before the Generic Pharmaceutical Association Annual Policy Conference on September 19, 2005, just days after the FDA had denied Aventis' Citizen Petition at issue here. http://www.gphaonline.org/AM/Template.cfm ?Section =Home&CONTENTID2234&TEMPLATE=/CM/ContentDisplay.cfin; at p. 21, et seq.*

change in the Agency's policy on the basis of data or information submitted in the Citizen Petition.

41. Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 41 of the Complaint and therefore DENIES each and every allegation contained therein. To the extent that Paragraph 41 relies on statements contained in the public record, those statements speak for themselves.

42. *As a general matter, the FDA has limited resources to devote to all aspects of drug regulation, including consideration and resolution of all Citizen Petitions that are filed. In addition, as a practical matter, the FDA must first review the issues raised in a Citizen Petition before it can be in a position to grant or deny a petition, even a frivolous one. As a result, while there is no statutory requirement that the FDA withhold approval of an ANDA while a Citizen Petition is pending, it is the practice of the FDA, well known in the pharmaceutical industry, to consider and respond to a Citizen Petition prior to approval of an ANDA. On this subject Mr. Buehler acknowledged, "[i]t is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the Citizen Petitions."*

42. Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 42 of the Complaint and therefore DENIES each and every allegation contained therein. To the extent that Paragraph 42 relies on statements contained in the public record, those statements speak for themselves.

43. *Given this regulatory scheme and practice, and the nature of the pharmaceutical industry (particularly the economics), the potential and incentive for abuse of the Citizen Petition process by brand name manufacturers is great.*

43. Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations of the Paragraph 43 of the Complaint and therefore DENIES each and every allegation contained therein.

E. *Aventis' Unlawful Scheme to Delay AB-Rated Generic Competition for Arava*

44. *Aventis' Arava (leflunomide) was approved for sale in the United States by the FDA on September 10, 1998, in strengths of 10 mg, 20 mg and 100 mg. The usual daily dose of Arava is 20 mg. The 10 mg dosage is used in patients who do not tolerate the 20 mg dose adequately.*

44. Aventis admits that the FDA approved its NDA for leflunomide on September 10, 1998, in strengths of 10mg, 20mg, and 100mg. Aventis further admits that the maintenance dose of Arava is 20mg, but that physicians whose patients who do not adequately tolerate the 20mg maintenance dose may prescribe a 10mg dose instead.

45. *The use of a "loading dose" of 100 mg per day for three (3) days is recommended in Arava's approved labeling. The use of the loading dose is not essential to the effective use of the product, and elimination of the loading dose may actually decrease the risk of adverse events for some patients.*

45. Aventis admits the allegations contained in the first sentence of Paragraph 45 of the Complaint. Specifically, the approved labeling (which relied on clinical trials incorporating the loading dose regimen) provides that "Due to the long half-life in patients with RA and

recommended dosing interval (24 hours), a loading dose is needed to provide steady-state concentrations more rapidly. It is recommended that ARAVA therapy be initiated with a loading dose of one 100 mg tablet per day for 3 days." Aventis denies the allegations of the second sentence of Paragraph 45 of the Complaint insofar as it suggests that the loading dose is not essential to the most effective use of the product. Aventis admits, however, that the approved labeling acknowledges that "Elimination of the loading dose regimen may decrease the risk of adverse events."

46. *As filer of the NDA for Arava, Aventis enjoyed the exclusive FDA regulatory right to market Arava in all three dosage forms for five (5) years pursuant to section 505(j)(5)(F)(ii) of the FDCA, even though Arava did not have patent protection from the generic competitors at issue here. In addition, because the FDA determined that, under section 505(A) of the FDCA, Arava was entitled to pediatric exclusivity, the period of exclusive marketing of Arava by Defendant was extended six (6) months. Defendant's exclusive right to market Arava ended on March 10, 2004. During these periods no generic manufacturer was entitled to even file an ANDA with the FDA seeking approval for an AB-rated generic version of Arava.*

46. Aventis DENIES the allegations of the first sentence of Paragraph 46 of the Complaint. Aventis admits, however, that it had exclusive marketing rights for all three dosage forms for five years following FDA approval of the Arava NDA, and that there were no patents listed in the Orange Book that would have entitled it to notice of the filing of any ANDAs. Aventis admits the allegations of the second, third, and fourth sentences of Paragraph 46 of the Complaint.

47. *With knowledge of the timing of the various exclusivity periods applicable to Arava, and the lack of patent protection, Aventis was fully aware of when generic manufacturers would be filing ANDAs and the approximate periods in which FDA would approve such ANDAs. Based on this knowledge, Aventis devised a strategy to delay entry of generic manufacturers into the market for 10 mg and 20 mg leflunomide tablets.*

47. Aventis DENIES each and every allegation of Paragraph 47 of the Complaint. Aventis further states that there were no patents listed in the Orange Book that would have entitled it to notice of the filing of any ANDAs, which are otherwise confidential documents pursuant to 21 C.F.R. § 314.430(b) and (d).

48. *In September 2002, four years after obtaining FDA approval for Arava, and over a year before its exclusivity was set to expire, Defendant stopped selling the 100 mg loading dose of Arava. Instead, Defendant began supplying the loading dose as a free sample to physicians in the form of a blister pack containing three 100 mg tablets of Arava.*

48. Aventis DENIES the allegations in the first sentence of Paragraph 48 of the Complaint to the extent it suggests that its decision to stop selling the 100mg loading dose related to the expiration of its marketing exclusivity. Aventis admits the allegations in the second sentence of Paragraph 48 of the Complaint.

49. *Defendant stopped selling the 100 mg tablets in anticipation of the loss of market exclusivity as a means of providing a pretext for interfering with generic entry into the more lucrative 10 mg and 20 mg markets. Providing the loading dose for free disincentivized any generic manufacturer from sponsoring an ANDA with respect to the 100 mg tablet, as the*

product was available free to physicians from Aventis. Defendant later attempted to use the fact that no ANDA filers were seeking approval for the 100 mg tablet to argue that any ANDA for the 10 mg and 20 mg dosages could not be approved unless and until (a) the ANDA also sought approval for the 100 mg dosage, or (b) the ANDA filer satisfied additional bioequivalence testing which was specifically not required by federal regulations.

49. Aventis DENIES each and every allegation of Paragraph 49 of the Complaint.

50. *As mentioned above, pursuant to 505(c)(3)(E)(ii) of the FDCA, no ANDA could be submitted until the expiration of Defendant's regulatory exclusivity period for Arava on March 10, 2004.*

50. Aventis DENIES the allegations of Paragraph 50 of the Complaint. Aventis admits, however, that pursuant to the FDCA, no ANDA seeking approval of a generic version of Arava could be submitted to the FDA until Aventis' marketing exclusivity expired on March 10, 2004.

51. *Not surprisingly, on or about March 10, 2004, several generic manufacturers, including Kali Laboratories, Barr Laboratories, TEVA Pharmaceuticals, Apotex Corp., and Sandoz, Inc., filed ANDAs with the FDA, each seeking approval to market AB-rated generic versions of 10 mg and 20 mg tablets of Arava (leflunomide).*

51. Aventis DENIES the allegations of Paragraph 51 of the Complaint. Aventis admits, however, that it now knows that on or about March 10, 2004, Kali Laboratories, Barr Laboratories, TEVA Pharmaceuticals, Apotex Corporation, and Sandoz, Inc. filed ANDAs seeking FDA approval to market generic versions of Arava.

52. *On March 31, 2005, more than a year after the various leflunomide ANDAs were filed, Aventis filed a Citizen Petition with the FDA, pursuant to 505(j) of the FDCA, in order to delay all AB-rated generic versions of Arava from entering the United States market. A copy of that Citizen Petition is attached hereto as Exhibit 2.*

52. Aventis DENIES each and every allegation of Paragraph 52 of the Complaint. Aventis admits, however, that on March 31, 2005 Aventis filed a citizen petition with the FDA, a copy of which was attached to the Complaint.

53. *Aventis' Citizen Petition urged the FDA to withhold approval of any ANDA that did not also seek approval of a 100 mg leflunomide tablet that is bioequivalent to Defendants Arava 100 mg tablets or did not establish in vivo bioequivalence between five 20 mg leflunomide tablets and one Arava 100 mg tablet.*

53. Aventis admits the allegations contained in Paragraph 53 of the Complaint, but notes that they are wholly divorced from the regulatory scheme governing abbreviated new drug applications, which (by definition) rely on the safety and efficacy studies supporting the original NDA as well as the approved labeling for the branded drug. Viewed in the context of those regulations, the citizen petition asked the FDA to refrain from approving any ANDAs unless they relied on a 100mg loading dose (since the clinical studies supporting Aventis' NDA for 20mg and 10mg tablets included a 100mg loading dose), and referred to that loading dose in any approved label (since the FDA required Aventis to include the 100mg loading dose in its approved label). Aventis did not object to any ANDA that sought approval for a 100mg tablet of its own, but asked the FDA to require any generic manufacturers seeking approval to substitute

5x20mg for 100mg tablets to provide additional testing demonstrating bioequivalence between the different dosage forms (as the FDA had required Aventis to do when it proposed the same substitution itself).

54. *Aventis' Citizen Petition, which was filed on the eve of the FDA' s approval of the various ANDAs for generic leflunomide, used arguments and citations that were known and available to Aventis well before it submitted the Citizen Petition to the FDA. The FDA's response to Aventis' Citizen Petition, issued on September 13, 2005, made special note of these facts. A copy of the FDA's response to Defendant's Citizen Petition is attached hereto as Exhibit 1.*

54. Aventis DENIES each and every allegation of Paragraph 54 of the Complaint. Aventis admits, however, that the FDA's September 13, 2005 response to Aventis' citizen petition, a partial copy of which was attached to the Complaint, referenced the prior availability of certain of the arguments and citations Aventis identified in the petition.

55. *Specifically, in its Citizen Petition, Aventis argued that in order to market a 10 mg or a 20 mg generic version of Arava, an ANDA applicant must provide evidence of bioequivalence of five of its 20 mg generic tablets to the 100 mg branded Arava tablet – even if the ANDA does not seek approval to sell a 100 mg generic tablet – or submit an ANDA for a 100 mg strength generic tablet. Aventis premised this argument on the fact that, while evaluating Aventis' NDA – which did seek approval for a 100 mg tablet – the FDA had required Aventis to provide evidence of bioequivalence between five 20 mg tablets of branded Arava and the 100 mg*

strength before Aventis could obtain approval for the use of five 20 mg tablets as the 100 mg "loading dose".

55. Aventis DENIES the allegations contained in the first sentence of Paragraph 55 of the Complaint insofar as they divorce Aventis' arguments from the regulatory scheme governing abbreviated new drug applications, which (by definition) rely on the safety and efficacy studies supporting the original NDA as well as the approved labeling for the branded drug. Aventis admits the allegations in the second sentence of Paragraph 55 of the Complaint to the extent they are viewed in light of the applicable regulatory scheme.

56. *Aventis also argued that any label for generic leflunomide 10 mg or 20 mg tablets for which the generic manufacturer did not also seek and obtain approval for a 100 mg loading dose would need to omit any mention of a loading dose and would therefore render the generic formulations "less effective" than Arava, and therefore not capable of final FDA approval under applicable FDA labeling regulations.*

56. Aventis DENIES each and every allegation of Paragraph 56 of the Complaint. Aventis admits, however, that in its citizen petition Aventis expressed concern that any ANDAs seeking approval of 10mg and 20mg—but not 100mg—leflunomide tablets might seek to substitute 5x20mg tablets for the 100mg loading dose (something generic manufacturers could not do without additional bioequivalence testing in light of the FDA's prior response to the same request) or might seek to exclude the loading dose altogether (something generic manufacturers could not do by availing themselves of the ANDA process).

57. *Specifically, Aventis' petition stated that, "Aventis believes that these [generic] applicants are instead seeking to include a loading dose of five 20 mg leflunomide tablets or seeking to exclude the loading dose [from the labeling] altogether." This was a false statement, and Aventis had no basis for making it. The ANDAs of the various generic manufacturers contained no proposal to use five 20 mg leflunomide tablets as a loading dose or to omit mention of a loading dose in their labeling. See Exhibit 1.*

57. Aventis DENIES each and every allegation in the second sentence of Paragraph 57. Aventis further states that because there were no patents listed in the Orange Book that would have entitled it to notice of the filing of any ANDAs (which are otherwise confidential documents pursuant to 21 C.F.R. § 314.430(b) and (d)), Aventis had now way of knowing whether any ANDAs had been filed or what they contained. Aventis admits the allegations in the first sentence of paragraph 57 of the Complaint. Because the ANDAs remain confidential and have not been produced yet in this litigation Aventis is without sufficient information or knowledge to form a belief concerning the truth of the allegations contained in the third sentence of the Paragraph 57 of the Complaint and therefore DENIES each and every allegation contained therein.

58. *Aventis knew its Citizen Petition was objectively baseless and a sham because, as a sophisticated pharmaceutical company with extensive experience with the FDA approval process, it was aware that (among other things) generic Arava labeling could indicate a 100 mg loading dose (a) regardless of whether or not the generic manufacturer marketed a 100 mg dose, and (b) without demonstrating bioequivalence of five 20 mg tablets to one 100 mg Arava tablet. It is clear Aventis' Citizen Petition was not submitted to influence FDA policy or address any*

legitimate concern about the efficacy or safety of generic leflunomide, but was submitted solely to forestall generic competition in the United States market for leflunomide during the time it would take the FDA to evaluate and respond to the Citizen Petition.

58. Paragraph 58 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 58 of the Complaint.

59. *Defendant's Citizen Petition ignored the fact that the FDCA and bioequivalence regulations do not require that an ANDA sponsor demonstrate equivalence between different strengths of its own product line, only that it demonstrate bioequivalence between the dosage of the drug which is the subject of the ANDA and the name brand drug of the same dosage. See 21 C.F.R. Part 320. Further, there are no regulations which require an ANDA applicant to seek approval for all strengths of the reference listed brand name drug (here, Arava).*

59. Aventis DENIES each and every allegation of Paragraph 58 of the Complaint. Aventis further states that it is without information or knowledge as to any other instance in which the FDA has approved generic maintenance doses relying on clinical studies incorporating a branded loading dose, or permitted the labeling for generic maintenance doses to refer to the branded loading dose.

60. *As the FDA response points out, the fact that generic manufacturers only sought to market the 10 mg and 20 mg did not necessitate that they omit any mention of a loading dose for leflunomide in their labeling. The FDA stated that, "[Aventis] seem[s] to ignore a third possibility: that the labeling for a generic leflunomide product can recommend a loading dose*

of 3 x 100 mg that can be accomplished by the use of an approved 100 mg tablet from a different manufacturer. Given the unusual manner in which the 100 mg tablet for the loading dose has been distributed by Aventis (i.e., in blister packs of 3, for free and only to, and at the request of, a physician) and the fact that there are circumstances when a loading dose should perhaps not be used, we do not find it unreasonable for a generic manufacturer to elect to market only the other dosage strengths." See, Exhibit 2, at p. 6.[3]

60. Aventis DENIES the allegations contained in Paragraph 60 to the extent that they presume Aventis could have known about the existence or content of the ANDAs and insofar as they suggest some precedent for permitting the approved labeling for generic maintenance doses to refer to a branded loading dose. To the extent that Paragraph 60 relies on statements contained in the public record, those statements speak for themselves.

61. *The FDA also found that the "[Aventis'] Comment acknowledges that an ANDA applicant that seeks approval of a 20-mg leflunomide tablet, but not a 100-mg tablet, could propose to 'reference [in the drug's label] a 100 mg tablet that the generic does not manufacture' (Comment at 3). You go on to assert that this option should not be permitted (Id.); however, you provide no explanation for your assertion, and, for the reasons discussed in the text above, we see no reasoned basis to accept it."*[4] *Exhibit 1 at p. 6, fn 14.*

---

[3] *See also, Exhibit 1, at pp. 6– 7,8 ("Labeling for generic leflunomide products approved in 10- and 20-mg strengths may reference a 100-mg leflunomide tablet that the generic sponsor does not produce. As reflected by existing precedents, ANDA sponsors may refer in their labeling to products they do not manufacture.... It is also not uncommon for brand name products to refer in their labeling to other drugs that are not provided by the sponsor of the brand name product (e.g., the labeling of Oncaspar – an Aventis product, recommends its use in combination with the following products not made by Aventis: vincristine; methotrexate, cytarabine, daunorubicin, and doxorubicin; also, the labeling of Eloxatin, owned by Sanofi-Synthelabo, Inc., recommends that it be used in combination with infusional 5-FU/LV[5-fluorouracil/leucovorin], which Sanofi-Synthelabo, Inc., does not supply).)"*

[4] *The FDA' s response to a Citizen Petition is considered an official position of the FDA. See 21 C.F.R. § 10.45(d). ("Unless otherwise provided, the Commissioner's final decision constitutes final agency action (reviewable in the courts under ...))"*

61. Aventis admits the allegations in Paragraph 61 of the Complaint, but states that it is without information or knowledge as to any other instance in which the FDA has approved generic maintenance doses relying on clinical studies incorporating a branded loading dose, or permitted the labeling for generic maintenance doses to refer to the branded loading dose. To the extent that Paragraph 61 relies on statements contained in the public record, those statements speak for themselves.

62. *On September 13, 2005, the FDA denied Aventis' Citizen Petition and also granted final approval to the ANDAs sponsored by Kali Laboratories, Barr Laboratories, TEVA Pharmaceuticals, Apotex Corp., and Sandoz, Inc., for the 10 mg and 20 mg dosage tablets of leflunomide. These generic manufacturers, as well as Prasco Laboratories, under an agreement with Defendant to sell an "authorized generic" version leflunomide, began selling generic Arava in the United States market on September 14, 2005.*

62. Aventis admits that the FDA denied Aventis' citizen petition on September 13, 2005 and that it subsequently learned that the FDA approved ANDAs sponsored by Kali Laboratories, Barr Laboratories, TEVA Pharmaceuticals, Apotex Corporation, and Sandoz, Inc. on the same day. Aventis further admits that on or about September 14, 2005, these manufacturers, along with Prasco Laboratories (under an agreement with Aventis to sell an authorized generic version of Arava), began selling generic leflunomide in the United States.

63. *As a direct and proximate result of Aventis' unlawful conduct, Plaintiff Louisiana Wholesale and the Class were denied the benefits of free and unrestrained competition in the market for leflunomide from March 31, 2005, the date of Aventis' Citizen Petition, until*

September 14, 2005, the date when generic leflunomide became available in the United States. The effects of Aventis' anticompetitive scheme may actually extended beyond September 14, 2005, as a result the economic realities of the pharmaceutical industry which cause the full extent and benefit of generic penetration to not occur immediately upon market entry.

63. Paragraph 63 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 63 of the Complaint.

64. *More specifically, Louisiana Wholesale and members of the Class were denied the opportunity to purchase lower-priced AB-rated generic versions of Arava, and were thereby forced to pay supra-competitive prices for leflunomide.*

64. Aventis DENIES each and every allegation of Paragraph 64 of the Complaint.

65. *Aventis' actions are part of, and in furtherance of, the illegal monopolization scheme alleged herein, and were authorized, ordered or done by Aventis' officers, agents, employees or representatives while actively engaged in the management of Aventis' affairs.*

65. Paragraph 65 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 65 of the Complaint.

66. *Aventis' illegal acts to delay the introduction and/or dissemination into the U.S. marketplace of any generic version of Arava resulted in Plaintiff and the Class paying more than they would have paid for leflunomide, absent Aventis' illegal conduct.*

66. Paragraph 66 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 66 of the Complaint.

F. ***Effect on Interstate Commerce***

67. *At all material times, Arava, manufactured and sold by Aventis, was shipped across state lines and sold to customers located outside its state of manufacture.*

67. Aventis DENIES the allegations contained in Paragraph 67 of the Complaint. Aventis admits, however, that it sold Arava tablets in the United States, and that those tablets were shipped across state lines during the five month period while the citizen petition was pending.

68. *During the relevant time period, in connection with the purchase and sale of Arava, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.*

68. Aventis admits that in connection with Aventis' sale of Arava tablets in the United States, monies and contracts were transmitted across state lines during the five month period while the citizen petition was pending.

69. *During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Aventis, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.*

69. Paragraph 69 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation in the first sentence of Paragraph 60. Aventis admits, however, that Aventis' sale of Arava tablets in the United States took place within the flow of interstate commerce.

70. *Aventis' exclusionary conduct impeded the sale of generic leflunomide in the United States, and unlawfully enabled Aventis to sell Arava at monopolistic, artificially inflated prices. By engaging in such conduct, Aventis harmed the competitive process, and illegally maintained its ability to extract supra-competitive prices from purchasers of leflunomide. But for Aventis' illegal conduct, generic competitors would have been able to compete for sales of 10 mg and 20 mg Arava in March 2005, and Plaintiffs, members of the Class, and other purchasers would have benefited from that competition by paying lower prices for leflunomide*

70. Paragraph 70 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 70 of the Complaint.

71. *There are no procompetitive justifications for Aventis' conduct. The conduct alleged above created no efficiency gains or increases in consumer welfare. On the contrary, Aventis' conduct substantially decreased or eliminated the efficiency gains that would otherwise have occurred through the earlier introduction of less expensive AB-rated generic versions of Arava that could be substituted at the pharmacy counter for branded Arava – efficiency gains that Congress and state legislatures intended to bring about when they enacted Hatch-Waxman and state generic substitution laws.*

71. Paragraph 71 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 71 of the Complaint.

72. *As a result of Aventis' unlawful and exclusionary conduct, Louisiana Wholesale and members of the Class continued to purchase branded Arava from Aventis at monopoly prices rather than generic leflunomide from generic manufacturers at lower prices and Arava from Aventis at lower prices.*

72. Paragraph 72 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 72 of the Complaint.

G. *Monopoly Power and Relevant Market*

73. *Direct proof exists that Aventis had monopoly power over the price of leflunomide. Such direct evidence includes transactional data showing a significant, non-transitory decline in leflunomide prices immediately upon entry of generic leflunomide that had not occurred until generic entry. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether Aventis had monopoly power.*

73. Paragraph 73 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 73 of the Complaint. Aventis further denies the assertion that Plaintiff is not required to define a relevant product market in assessing whether Aventis had monopoly power.

74. *Assuming, arguendo, that a relevant market needs to be defined, the relevant product market is leflunomide, i.e., Arava and any AB-rated generic equivalents. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Aventis' ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which leflunomide is prescribed.*

74. Paragraph 74 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES the allegations in the first, third, and fourth sentences of Paragraph 74 of the Complaint. Aventis admits, however, that the relevant geographic market is the United States and its territories.

75. *Through the anticompetitive conduct alleged herein, Aventis was able to profitably charge supra-competitive prices for leflunomide without losing substantial sales, and thus, by definition, maintained monopoly power with respect to leflunomide sold in the United States.*

75. Paragraph 75 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 75 of the Complaint.

76. *Prior to generic entry in September 2005, Aventis' market share in the relevant market was 100%. After market entry by generic manufacturers with much cheaper generic version of Arava, Aventis' market share for this drug product declined dramatically in a short period of time.*

76. Paragraph 76 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 76 of the Complaint.

H. *Effects on Competition and Damages to Plaintiff and Class*

77. *Aventis' actions were intended to suppress, rather than promote, competition on the merits, and have had precisely the intended effect.*

77. Aventis DENIES each and every allegation of Paragraph 77 of the Complaint. Aventis further states that the purpose of its citizen petition was to ensure that the FDA hold manufacturers seeking to market a generic version of leflunomide to the same safety and effectiveness standards to which the FDA held Aventis.

78. *Louisiana Wholesale and members of the Class have been injured in their business and property by reason of Aventis' unlawful monopolization. Plaintiffs injury consists of paying higher prices for leflunomide than would have been paid in the absence of Aventis' illegal conduct. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Aventis' conduct unlawful.*

78. Paragraph 78 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 78 of the Complaint. Aventis further DENIES that Plaintiff and any putative class

members are entitled to the relief sought in the Complaint or to any other relief whatsoever from Aventis.

79. *Defendant's exclusionary conduct delayed the sale of generic leflunomide in the United States, and unlawfully enabled Aventis to sell Arava at artificially inflated prices. But for Defendant's illegal conduct, multiple generic competitors would have been able to successfully market AB-rated generic versions of Arava capsules by March 2005 – approximately five months before they were actually able to obtain FDA approval and come to market.*

79. Paragraph 79 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 79 of the Complaint. Aventis further DENIES that Plaintiff and any putative class members are entitled to the relief sought in the Complaint or to any other relief whatsoever from Aventis.

80. *If manufacturers of generic Arava had entered the marketplace and effectively competed with Aventis earlier, as set forth above, Louisiana Wholesale and other members of the Class would have substituted lower-priced generic leflunomide for the higher-priced brand name Arava for some or all of their leflunomide requirements, and/or would have received a lower price (and/or discounts) on some or all of their remaining Arava purchases.*

80. Aventis DENIES each and every allegation of Paragraph 80 of the Complaint. Aventis further DENIES that Plaintiff and any putative class members are entitled to the relief sought in the Complaint or to any other relief whatsoever from Aventis.

COUNT I – Monopolization in Violation of Section 2 of the Sherman Act

81. *Plaintiff repeats, and incorporates by reference, the allegations above in ¶91 1 – 80 above.*

81. Aventis DENIES each and every allegation of Paragraph 81 of the Complaint, except insofar as such allegations may have been specifically admitted in response to the previous allegations.

82. *Aventis used willful and exclusionary means as part of a scheme described herein to improperly maintain and extend their monopoly power in the leflunomide market, as detailed above.*

82. Paragraph 82 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 82 of the Complaint.

83. *The goal, purpose and effect of Aventis' scheme was to prevent, delay, and/or minimize the success of the entry of AB-rated generic leflunomide competitors which would have sold generic leflunomide in the United States at prices significantly below Defendant's prices for Arava, which would have effectively caused the average market price of leflunomide to decline dramatically.*

83. Aventis DENIES each and every allegation of Paragraph 83 of the Complaint.

84. *The goal, purpose and effect of Aventis' scheme was also to maintain and extend its monopoly power with respect to leflunomide. Aventis' illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic*

version of Arava enabled Aventis to continue charging supra-competitive prices for leflunomide without a substantial loss of sales.

84. Paragraph 84 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 84 of the Complaint. Aventis further DENIES that Plaintiff's proposed relevant market definition is legally sufficient.

85. *As a result of Aventis' illegal conduct, Plaintiff and the Class paid more than they would have paid for leflunomide, absent Aventis' illegal conduct. But for Aventis' illegal conduct, competitors would have begun marketing generic versions of Arava well before they actually did.*

85. Paragraph 85 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 85 of the Complaint.

86. *If manufacturers of generic leflunomide entered the market and competed with Aventis in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic leflunomide for the higher-priced brand name Arava for some or all of their leflunomide requirements, and/or would have received lower prices on some or all of their remaining Arava purchases.*

86. Aventis DENIES each and every allegation of Paragraph 86 of the Complaint.

87. *Aventis' scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for leflunomide in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.*

87. Paragraph 87 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Aventis DENIES each and every allegation of Paragraph 87 of the Complaint.

VI. *JURY TRIAL DEMANDED*

88. *Plaintiff demands trial by jury on all issues so triable.*

88. Aventis admits that Plaintiff demands a jury trial on all issues so triable.

VII.*PRAYER FOR RELIEF*

WHEREFORE, *Plaintiff, on behalf of itself and the Class, respectfully prays that:*

(i) The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

(ii) The acts alleged herein be adjudged and decreed to be unlawful and willful acts of monopolization in restraint of trade in violation of Section 2 of the Sherman Act;

(iii) The Class be awarded three-fold the damages determined to have been sustained by the Class, and that judgment be entered against Aventis in favor of the Class;

(iv) The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

(v) The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

* * *

To the extent that any response is required to the Prayer for Relief, Aventis DENIES each and every allegation contained therein.

Aventis is entitled to, and hereby demands, a trial by jury on all issues so triable.

AFFIRMATIVE DEFENSES

A. FAILURE TO STATE A CAUSE OF ACTION

Plaintiff's and the proposed class members' claims fail to allege facts sufficient to state a cause of action upon which relief may be granted against Aventis, and further fail to state facts sufficient to entitle Plaintiff (or the proposed class members) to the relief sought or any other relief whatsoever from Aventis.

B. LACK OF STANDING

Plaintiff's claims fail, in whole or in part, because it lacks standing to assert the antitrust claims alleged in the Complaint.

C. INTERVENING OR SUPERSEDING CAUSE

Plaintiff's claims are barred, in whole or in part, because the alleged injuries and damages, if any, resulted from an intervening or superseding cause.

D. LACK OF SUBJECT MATTER JURISDICTION

This Court lacks subject matter jurisdiction over the purported class members' claims against Aventis because there is no case or controversy within the meaning of Article III of the Constitution of the United States.

E. LACK OF DAMAGES

Plaintiff's and the proposed class members' claims for damages are barred because they cannot prove actual damages or because of the speculative nature of all or part of the damages allegedly sustained.

F. DUE PROCESS AND ACCESS TO COURTS

The certification and maintenance of this action as a class action would violate Aventis's due process rights under the Fifth Amendment and the Fourteenth Amendment to the United States Constitution and would deny Aventis the right of access to the courts to the extent that the certification and maintenance of a class action would deprive Aventis of procedural and substantive safeguards and of traditional defenses to liability.

G. SEVENTH AMENDMENT

The certification and maintenance of this action as a class action would violate Aventis's right to a single jury trial as provided by the Seventh Amendment to the United States Constitution.

Dated: January 3, 2008

Respectfully submitted,

___/s/ Christopher R. Farrell
John M. Majoras
Julia E. McEvoy (admitted *pro hac vice*)
Christopher R. Farrell (admitted *pro hac vice*)
Jones Day
51 Louisiana Avenue, NW
Washington, DC 20001
Tel.: 202-879-3939
Fax: 202-626-1700

Counsel for
SANOFI-AVENTIS U.S. LLC *and*
AVENTIS PHARMACEUTICALS INC.

CERTIFICATE OF SERVICE

I, Christopher R. Farrell, certify that the foregoing Answer and Affirmative Defenses was served on January 3, 2008, on the counsel listed below in the manner(s) indicated below:

Via ECF:

Bruce E. Gerstein
Barry S. Taus
Anne K. Fornecker
GARWIN GERSTEIN & FISHER LLP
1501 Broadway, Suite 1416
New York, NY 10036
Tel.: 212-398-0055
Fax: 212-764-6620
bgerstein@garwingerstein.com
btaus@garwingerstein.com
afornecker@garwingerstein.com

Eric L. Cramer
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Tel.: 1-800-424-6690
Fax: (215) 875-4604
ecramer@bm.net

Richard Jo Kilsheimer
Linda Nussbaum
KAPLAN FOX & KILSHEIMER, LLP
850 Third Avenue, 14th Floor
New York, NY 10022
Tel.: 212-687-1980
Fax: 212-687-7714
lnussbaum@kaplanfox.com
rkilsheimer@kaplanfox.com

Adam Moskowitz
Thomas A. Tucker Ronzetti
KOZYAK TROPIN & THROCKMORTON
2525 Ponce De Leon Blvd, 9th Floor
Miami, FL 33134
Tel.: (305)-372-1800
Fax: (305)-372-3508
amm@kttlaw.com
tr@kttlaw.com

Stuart E. Des Roches
Charles Ferrier Zimmer, II
ODOM & DES ROCHES, LLP
Suite 2020, Poydras Center
650 Poydras Street
New Orleans, LA 70130
Tel.: (504) 522-0077
Fax: (504) 522-0078
stuart@odrlaw.com
czimmer@odrlaw.com

Via UPS

David P. Smith
W. Ross Foote
PERCY, SMITH & FOOTE LLP
720 Murray Street
P.O. Box 1632
Alexandria, LA 71309
Tel: 318-445-4480
Fax: 318-487-1741

Brent Barriere
Susie Morgan
PHELPS DUNBAR
Canal Place, Suite 2000
365 Canal Street
New Orleans, LA 70130

John Gregory Odom
ODOM & DES ROCHES, LLP
Suite 2020, Poydras Center
650 Poydras Street
New Orleans, LA 70130
Tel.: (504) 522-0077
Fax: (504) 522-0078

Daniel Berger
David F. Sorensen
Peter Russell Kohn
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Tel.: 1-800-424-6690
Fax: (215) 875-4604

/s/ Christopher R. Farrell
Christopher R. Farrell